IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. JOHN UNDERWOOD **Plaintiff,** **v.** **GENENTECH, INC. and ROCHE HOLDINGS, INC.** **Defendants.**	**CIVIL ACTION No. 03-3983**

DEFENDANT'S DISCOVERY SUBMISSION UNDER RULE 26(f)(3)(B)

I. INTRODUCTION

Rule 26(f)(3)(B) calls upon the parties to submit their respective views on the subjects on which discovery may be needed and, among other things, whether discovery should be focused on particular issues. This submission constitutes defendant Genentech's views on those subjects.

II. LIKELY SUBJECTS OF DISCOVERY

Identifying Contentions and Claims: Genentech's discovery will focus initially on determining what claims for reimbursement are at issue. Under Count I, Genentech will need to discover which physicians Relator alleges were influenced by the company's allegedly unlawful statements, which claims submitted by those physicians Relator alleges were fraudulent, and how Genentech allegedly caused these physicians to submit such allegedly fraudulent claims. Likewise, under Count II, the company will need to discover the identity of the members of the Advisory Boards (out of a universe of approximately 1500 Advisory Board participants) to whom Relator alleges the company paid unlawful remuneration and which claims submitted by those physicians Relator alleges were fraudulent.

In light of claims, physicians and other specifics disclosed by Relator, Genentech then anticipates challenging Relator's evidence on each element, and to that end, conducting discovery as follows:

Underlying Conduct: Genentech anticipates that it may need to conduct discovery to identify the specific communications to physicians regarding off-label uses that Relator contends were unlawful, whether those communications were true or false, and whether they otherwise violated the law. As to Count II, the company anticipates possible discovery concerning the company's Advisory Boards, whether the compensation paid to the participating physicians was appropriate to the services they provided, whether the payments were made with the requisite intent to induce the purchase or order of Rituxan reimbursed by Medicare, and whether any subsequent Rituxan prescriptions by these physicians were in exchange for the company's payments.

Fraudulent Claims: Genentech anticipates that is may need to conduct discovery on the issue of "medical necessity" – i.e., if Relator's theory of the case is that the claims at issue were fraudulent because they were not medically necessary, the parties will need to conduct discovery from treating physicians as well as experts.

Causation: Genentech anticipates it may need to conduct discovery on the issue of whether its alleged unlawful conduct (fraudulent statements or kickbacks) in fact "caused" each of the physicians to be identified by the Relator to prescribe Rituxan off-label, or whether each of those physicians exercised his or her own professional judgment about the medical necessity of each treatment.

Materiality: Genentech anticipates that is may need to conduct discovery on the "materiality" of each allegedly false or fraudulent claim. Different off-label uses were placed "on compendia" at different times, which required the government to reimburse a physician for these off-label uses. Moreover, the numerous Medicare carriers around the country that had statutory discretion to cover off-label, off-compendial uses had different policies about covering Rituxan for off-label, off-compendial uses; these policies also varied over time. To explore these issues, Genentech may need to conduct third-party discovery of the Centers for Medicare and Medicaid Services ("CMS"), the various carriers around the country, as well as the Medicaid agencies in some or all of the 50 states. In addition, discovery may involve the National Cancer Institute, the Food and Drug Administration, and other agencies of the Department of Health & Human Services. Because this discovery involves the Government or its agents, it could implicate each of the relevant agency's "Touhy" regulations, see 5 U.S.C. § 301; United States v. Touhy, 340 U.S 462 (1951). Although Genentech is hopeful that it will be able to obtain such information in an efficient manner, the time required to obtain such information will ultimately depend on the responsiveness of the relevant government agencies, which Genentech cannot at this time predict.

Knowledge: Genentech anticipates possible discovery on the issue of whether it "knew" that any claims submitted by physicians were false or fraudulent, and whether the Government (for example, FDA) knew of the off-label use of Rituxan.

Damages: Genentech anticipates that is may need to conduct discovery on the issue of whether (or to what extent) the Government suffered any damages "because of" its conduct.

Relator: Either as part of the discovery above or separately, Genentech expects to conduct discovery of the Relator to determine the basis of his claims and his credibility and to discover and test the credibility of any ostensibly corroborating evidence such as testimony from associates of the Relator.

Date: July 15, 2010

Respectfully submitted,

GENENTECH, INC.

By: /s/ Robert E. Welsh, Jr.

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CERTIFICATE OF SERVICE

I, Robert E. Welsh, Jr., do hereby certify that on this date I caused a true and correct copy of the foregoing document to be served upon the following counsel via electronic mail:

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Date: July 15, 2010